

REMARKS

The Examiner has rejected claims 1, 4-5, 7-12 and 17-18 under 35 U.S.C. 103 as being unpatentable over Borud et al. Applicant respectfully disagrees with this rejection and asks for reconsideration. The Borud reference describes the preparation of potato proteins using “not less than 200ppm sulphur dioxide or sulphite...” in conjunction with “adjusting the pH to 4.6 or lower.” These limitations are very specific and have been eliminated in the present invention. SO₂ is a hazardous gas which is a known contributor to acid rain. In the present invention, the addition of SO₂ is eliminated through the use of an organic acid. The present invention describes a reaction that results in an isolated high purity proteinase inhibitor fraction and the reaction uses safe and non-destructive processing aids, along with closely monitored time and temperature profiles.

The Examiner’s statement that “one of ordinary skill in the art would have been motivated to substitute hydrochloric acid for an organic acid [sic] because the ordinary artisan would have had a reasonable expectation that an organic acid and hydrochloric acid would act as functional equivalents in lowering the pH of the extraction medium” is incorrect. Organic acid and hydrochloric acid will not act as functional equivalents. Organic acids don’t completely dissociate and are thus self-buffering. These acids have a known pKa, which is a reflection of a compound’s propensity to give up or accept a hydrogen ion (i.e. pKa reflects how much an acid will dissociate). The strong acids, such as HCl, don’t have pKas, and, as such, completely dissociate. The self-buffering quality of organic acids in the present invention allows for the liberation of the protein without the risk of degradation/denaturation associated with prior art reactions that employ HCl. Organic acid and HCl cannot be “functional equivalents” in the claimed

method, as adding HCl will result in the degradation/denaturation of the protein, while organic acid will not.

The Examiner rejects claim 6 under 103(a), citing Borud in view of Pearce or Bryant and claims 13-16, citing Borud in view of Ryan. None of the cited prior art describes the use of an organic acid in conjunction with a salt to simultaneously liberate and extract the target proteins. These prior art references use HCl, ethanol, urea, etc. to extract. In addition, the cited art does not describe or suggest the time and temperature effects on the final purity of the recovered protein fraction that are described in the present application.

The application has been amended to correct minor informalities, and to more particularly point out and distinctly claim the subject matter which Applicant regards as the invention so as to place the application, as a whole, into a prima facie condition for allowance. Great care has been taken to avoid the introduction of new subject matter into the application as a result of the foregoing modifications.

Accordingly, the purpose of the claimed invention is not taught nor suggested by the cited references, nor is there any suggestion or teaching that would lead one skilled in the relevant art to combine the references in a manner that would meet the purpose of the claimed invention. Because the cited references, whether considered alone, or in combination with one another, do not teach nor suggest the purpose of the claimed invention, Applicant respectfully submits that the claimed invention, as amended, patentably distinguishes over the prior art, including the art cited merely of record.

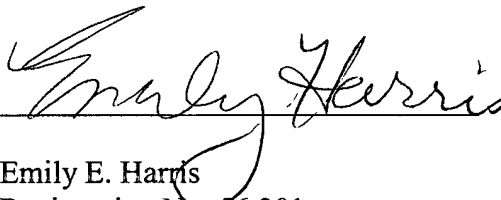
Based on the foregoing, Applicant respectfully submits that claims 1-18 are in condition for allowance at this time, patentably distinguishing over the cited prior art.

Accordingly, reconsideration of the application and passage to allowance are respectfully solicited.

The Examiner is respectfully urged to call the undersigned attorney at (515) 288-2500 to discuss the claims in an effort to reach a mutual agreement with respect to claim limitations in the present application which will be effective to define the patentable subject matter if the present claims are not deemed to be adequate for this purpose.

Respectfully submitted,

Date: 4/14/05

A handwritten signature in black ink, appearing to read "Emily Harris", written over a horizontal line.

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